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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/510,386

10/04/2004

Jens Tonne Andersen

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EXAMINER

VOGEL, NANCY S

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

10/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/510,386

Applicant(s)

ANDERSEN ET AL.

Examiner

Nancy T. Vogel

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/4/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

Claims 23-42 are pending in the case.

Receipt of the Information Disclosure Statement on 10/4/04 is acknowledged.

### ***Election/Restrictions***

Applicant's election with traverse of the polypeptide shown in SEQ ID NO:134, in the reply filed on 2/26/07 is acknowledged. The traversal is on the ground(s) that a search of all of the groups would not be an undue burden. This is not found persuasive because it is maintained that a search of more than one sequences would be a burden, since there is apparently no overlap in subject matter between each sequence, and no shared structural features or function. Furthermore the automated search of multiple amino acid or nucleic sequences requires burdensome database searches which would unduly tax the systems of the search facility.

The requirement is still deemed proper and is therefore made FINAL.

Claimed subject matter other than that limited to SEQ ID NO: 134, is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/26/07.

### ***Claim Objections***

Claims 23, 24, 26-42 are objected to because of the following informalities: the claims contain subject matter that was non-elected, i.e. those sequences shown in SEQ ID NO:2-133, 135-248. Appropriate correction is required.\

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection is based on the Guidelines for the Examination of Patent

Applications under the 35 U.S.C. 112, first paragraph "Written Description published in the Federal Register (Volume 66, Number 4, Pages 1099-1111).

Claim 23 is drawn to a *B. licheniformis* mutant strain which is mutated in a gene encoding a secreted protein having at least 80% sequence identity to SEQ ID NO:134, and which secretes at least 5% less of the secreted polypeptide than the parent host cell. Claims 23-42 are genus claims in terms of strains comprising any mutations in any gene encoding any secreted polypeptide having at least 80% sequence identity to SEQ ID NO:134, and which result in at least 5% less of the secreted polypeptide. The disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all the mutations in the gene encoding SEQ ID NO:134 which result in 5% less secretion of the resultant polypeptide, and further, cannot envision all of the genes encoding polypeptides which are at least 80% homologous to SEQ ID NO:134 and which are

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secreted polypeptides in *B. licheniformis*. While the specification provides guidance regarding the polypeptide of SEQ ID NO:134 and the gene encoding said polypeptide, there is no disclosure of related polypeptides or genes encoding them. Further, there is disclosed only deletions of the gene encoding SEQ ID NO:134, which would result in at least 5% less of the secreted polypeptide. Furthermore, there is no structure-function analysis of the disclosed polypeptide shown in SEQ ID NO:134 to provide guidance on the essential regions of the protein that could be modified and retain function as a secreted polypeptide. Therefore, the specification does not describe the claimed *B. licheniformis* mutant host cells in such full, clear, concise and exact terms so as to indicate that Applicant has possession of the method at the time of filing the present application. Thus, the written description requirement has not been satisfied.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NTV  
9/28/07

  
NANCY VOGEL  
PRIMARY EXAMINER